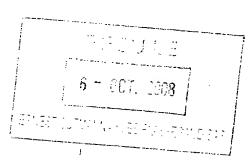




European Patent Office Postbus 5818 2280 HV Rijswijk NETHERLANDS Tel: +31 70 340 2040 Fax: +31 70 340 3016



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Substantive Examiner Name: Rosin, Oliver Tel: +31 70 340 - 8925

Application No. 01 970 984.9 - 1223	Ref. B5635-CA	Date 02.10.2008	
Applicant PROGENICS PHARMACEUTICALS, INC.			

### Result of consultation

A copy of the result of consultation of 19.09.2008 is enclosed for your information.



Rosin, Oliver
For the Examining Division

Enclosure(s):

Copy of result of consultation (Form 2036)

Applicants: Graham P. Allaway et al.

Serial No.: 09/888,938 Filed: June 25, 2001

Exhibit 10



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Application	No.
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01 970 984.9

Consultation by	telephone with t	he applicant	/representative
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### **Participants**

Applicant:

**Progenics Pharmaceuticals** 

Representative:

Sellin

Member(s) of the

Examining Division:

Rosin, Oliver

# Result of consultation

Examiner aksed for the provision of a technical effect resulting from the application of the antibody and the peptide at different times as well as for support in the description. Applicant wants to continue the proceedings in writing.



19.09.2008	Rosin, Oliver
Date	Examiner



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Application No. 01 970 984.9 - 1223	Ref. B5635-CA	Date 02.10.2008
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# Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and insofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

#### of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).



Rosin, Oliver Primary Examiner For the Examining Division

Enclosure(s):

4 page/s reasons (Form 2906)

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1

Demande nº:

Application No.: 01 970 984.9

The examination is being carried out on the following application documents:

**Description, Pages** 

1-100

as published

Sequence listings part of the description, Pages

1-5

as published

Claims, Numbers

1-8

received on

16.04.2008 with letter of

08.04.2008

**Drawings, Sheets** 

1/32-32/32

as published

Observations are hereby presented which take into account the communication of 28.09.2007 and your letter dated 08.04.2008.

The amendments filed with the letter dated 05.08.2005 do not introduce subject-matter which extends beyond the content of the application as filed, in the sense of Article 123(2) EPC.

# Inventive Step (Art 56 EPC)

The present application does not meet the requirements of Article 52(1) EPC, because the

Anmelde-Nr. Demande n°:

Application No.: 01 970 984.9

subject-matter of claims 1-4 and 6-8 does not involve an inventive step in the sense of Art 56 EPC.

2

Document D1 is considered to be the closest prior art to the subject-matter of claim 1 and discloses (the references in parentheses applying to this document): the use of "a composition for inhibiting HIV-1 infection comprising at least two compounds in synergistically effective amounts for inhibiting HIV-1 infection, wherein at least one of the compounds prevents the productive interaction between HIV-1 and an HIV-1 fusion co-receptor." (claims 1, 63 and 64). D1 discloses "The composition of claims 1 or 2 wherein the co-receptor is a chemokine receptor" (claim 3) and "The composition of claim 3, wherein the chemokine receptor is CCR5 or CXCR4." (claim 4) as well as "In another embodiment of the above compositions, at least one compound is an antibody and at least one compound is a chemokine or chemokine derivative. In this composition, the compounds are in an appropriate ratio. The ratio ranges from 100:1 to 1000:1. In another embodiment of the above compositions, at least one compound binds to the gp41 subunit of the HIV-1 envelope glycoprotein. In one embodiment, at least one compound is the T-20 peptide inhibitor of HIV-1 entry" (p14). D1 discloses that "This invention provides an anti-CCR5 monoclonal antibody. The antibody includes but is not limited to the following: ... and PA14 (ATCC Accession No. HB-12610)" (p20) as well as methods for preventing HIV-1 infection (claims 63 and 64).

The subject-matter of claim 1 therefore differs from this known from D1 in that both compounds are to be administered at different time points.

There is no technical effect.

The problem to be solved by the present invention may therefore be regarded as "how to provide a different use".

The solution proposed in claim 1 of the present application cannot be considered to involve an inventive step (Articles 52(1) and 56 EPC), for the following reasons: Except for the fact that the term "at a different time" is highly unclear and not specified further (refer to the objection under Art 84 EPC below), it seems to have been merely added to confer novelty over D1, because this feature does not at all provide a technical effect. One basis for the acknowledgement of an inventive contribution is however the provision of a technical effect. As this effect is absent the administration of the two compounds both known from D1 is thus an alternative to the simultaneous application suggested in D1. In the absence of a technical effect the skilled person would choose the sequential administration of the two compounds instead of the simultaneous to arrive at

Demande nº:

Application No.: 01 970 984.9

the solution of providing a different use without applying inventive skill due to the fact that this is an obvious alternative.

The same reasoning applies, mutatis mutandis, for the matter of claims 2-4 and 6-8.

Claims 1-4 and 6-8 are therefore not inventive (Art 56 EPC).

Representative argues as well that D1 does not disclose a different route of administration. In the absence of a technical effect and the obviousness of an alternative route of administration this comment is obsolete.

Post published evidence will not be accepted for both the route of administration as well as for the administration at different time points (T1329/04).

## Art 84 EPC)

The term "is administered ... at a different time" encompasses time ranges which could start with e.g. "is administered 1 millisecond after" up to e.g. "is administered 1 year after", but also encompasses "administered at 8 o'clock in the morning" and every possible time of day or even season, e.g. "PA14 is administered in winter and T-20 in summer". Thus the skilled person does not know what "is administered ... at a different time" really means. After consulting the description the skilled person does indeed find only one occurrence of this feature: "In one embodiment, the compounds are administered to the subject at different times" (p40 lines 9-11). Thus this term should be clarified further (Art 84 EPC) or better deleted.

### Conclusions

The applicant is requested to file new claims which take account of the above comments.

As there is a technical effect derivable from the administration of both compounds at a molar ratio of 1:30 (fig 4) which was not foreseen in D1, this feature, incorporated into the independent claims, could render the subject matter allowable under the EPC.

When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims. Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage, not to add

Datum Date Date

02.10.2008

Sheet Feuille

Anmelde-Nr.: Demande n°:

Application No.: 01 970 984.9

subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

Unless a recognisable effort is made towards a prompt compliance with the EPC requirements in the reply to this communication, summons to oral proceedings will be issued as the next official action as requested.